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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,126	10/04/2005	Koji Sode	3691-0114PUS1	9547
2292 7590 09/11/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER MEAH, MOHAMMAD Y	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 09/11/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

Application No.

10/520,126

Applicant(s)

SODE, KOJI

Examiner

Mohammad Meah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/1/07
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 20-32 is/are pending in the application.
- 4a) Of the above claim(s) 20-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 24-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/1/07
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_

### **DETAILED ACTION**

Claims 1, 20-32 are pending. Claims 1-5 and 24-25 were examined in the previous action. With supplemental amendment of this application, the applicant, on dates 6/1/07, cancelled claims 2-19, amended claims 1, 25 and added new claims 26-32. As amended claims 26-32 are within the scope of the elected invention and therefore is examined herewith. Claims 20-23 remain withdrawn as drawn to non-elected invention.

#### ***Claim Rejections***

#### ***35 U.S.C 112 Rejection***

#### ***35 U.S.C 112 1ST paragraph Rejections Written Description requirement***

#### ***Rejections:***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 24-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to any water soluble mutant pyrroloquinoline quinine glucose dehydrogenase (PQQGDH) wherein said PQQGDH comprises any mutant PQQDH having one or more amino acid residue substituted in SEQ ID NO:1. These claims encompass an unlimited number of substitutions in SEQ ID NO:1. The specification teaches the structure of SEQ ID NO: 1. The specification fails to describe other representative species by any identifying characteristics or properties other than high selectivity for glucose. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicants at page 7 of their amendment arguing against rejection of claims under 35 U.S.C. 112, first paragraph written description state that rejection of claims under 35 U.S.C. 112, first paragraph written description is not proper because pending claims require specific substitution in specific location of SEQ ID NO: 1. The argument is not found persuasive because while the claims require a specific mutation, they are sufficiently broad as to encompass any additional amino acid residue substitution in any location of SEQ ID NO: 1. Therefore, as explained above one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

***35 U.S.C 112 1ST paragraph Rejections enablement requirement Rejections:***

Claims 1 and 24-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modified PQQGDH of SEQ ID NO: 1

wherein Gln192 or leu193 or Asp167 and Asn452 are replaced by other amino acids, does not reasonably provide enablement for any mutant PQQDH having one or more amino acid residue substituted in SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1 and 24-32 are so broad as to encompass any PQQGDH derived from any source wherein any amino acid is modified from amino acid of SEQ ID NO: 1 wherein at least one of residues 192, 193 or 167 and 452 is modified. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of PQQGDH variants broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of only a few PQQGDH variants.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the

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desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification while describe the mutation of Gln192 or leu193 or Asp167 and Asn452 by other amino acids amino acid residues of SEQ ID NO: 1 does not support the broad scope of the claims which encompass any PQQGDH derived by mutation of any one or more amino acid residue of SEQ ID NO:1, because the specification does not establish: (A) structure of PQQH protein wherein any amino acid residue of PQQGDH of SEQ ID NO: 1 be modified to the attain desired selectivity for glucose ; (B) the general tolerance of PQQGDH to modification of such mutation of the PQQGDH sequence and extent of such tolerance; (C) a rational and predictable scheme for modifying any residue from SEQ ID NO: 1 of the PQQGDH with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly encompass any PQQGDH derived by mutation of any one or more amino acid residue of SEQ ID NO:1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19

24 (CCPA 1970)). Without sufficient guidance, determination of PQQGDH variants, having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988).

Against 112 enablement rejection, Applicant argue that rejection of claims under 35 U.S.C. 112, first paragraph enablement not proper because pending claims require specific substitution in specific location of SEQ ID NO: 1. The argument is not found persuasive because, while the claims require a specific mutation, they are sufficiently broad as to encompass any additional amino acid residue substitution in any location of SEQ ID NO: 1. . The argument is not found persuasive because any mutant PQQGDH derived by mutation of any one or more amino acid residue of SEQ ID NO:1. is a large variant genus potentially include many proteins with diverse structures. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification. As previously stated the specification does not establish: (A) structure of PQQH protein wherein any amino acid residue of PQQGDH of SEQ ID NO: 1 be modified to the attain desired selectivity for glucose ; (B) the general tolerance of PQQGDH to modification of such mutation of the PQQGDH sequence and extent of such tolerance; (C) a rational and predictable scheme for modifying any residue from SEQ ID NO: 1of the PQQGDH with an expectation of obtaining the desired biological function; and (D) the specification

provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

**CLAIM Rejection - 35 U.S.C 102**

**35 U.S.C 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 24-27,30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kratzsch et al. (WO 02/34919, priority on pct filing date 10/20/01 from IDS). Kratzsch et al. teach modified water soluble PQQGDH of *Acinetobacter calcoaceticus* wherein one or more amino acid at position 168, 169 and 428 of wild-type PQQGDH of *Acinetobacter calcoaceticus*( SEQ ID NO: 1 of the instant application) is mutated. Sode et al. teach a kit comprising said modified water soluble PQQGDH. Kratzsch et al. teach a kit comprising said modified water soluble PQQGDH.

Claims 1, 24-27,30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sode et al. (WO 00/61730). Sode et al. teach modified water soluble

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PQQGDH of *Acinetobacter calcoaceticus* wherein one or more amino acid at position 168, 169 and 428 of SEQ ID NO: 1 (which is 100% identical to applicants SEQ ID NO:1) is mutated.

Claims 1, 24-27,30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sode et al. (WO 00/66744). Sode et al. teach modified water soluble PQQGDH of *Acinetobacter calcoaceticus* wherein one or more amino acid at position 168, 169 and 428 of SEQ ID NO: 1 (which is 100% identical to applicants SEQ ID NO:1) is mutated. Sode et al. teach a kit comprising said modified water soluble PQQGDH.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed M. Y. Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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